



UNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NO. **FILING DATE** **FIRST NAMED INVENTOR** **ATTORNEY DOCKET NO.**

09/656,435 09/06/00 ITAI

09/06/00

FIRST NAMED INVENTOR

ATTORNEY DOCKET NO.

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EXAMINER

LIN, T

ART UNIT	PAPER NUMBER
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PAPER NUMBER

1631

DATE MAILED:

06/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/656,435	ITAI ET AL.	
	Examiner	Art Unit	
	Jerry Lin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4 and 5 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4 and 5 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- J. L.a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. PCT/JP93/00365.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/JP93/00365, filed on March 26, 1993.

Specification

2. The abstract of the disclosure is objected to because abstract has more than one paragraph. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the process using AMBER as disclosed in the specification, does not reasonably provide enablement for other algorithms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with

these claims. The test of enablement was cited in *re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Both claim 4 and 5 are broad claims drawn to outputting information of stable docking structures. However, the specification does not provide other methods for finding a stable docking structure. For example, other programs such as CHARMM do not have the ability to calculate torsional restraints as in AMBER. Without this function from AMBER, the practitioner could not cover all docking structures or select a stable docking structure by rotating torsion angles.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In instant claim 4, there are at least two conflicting interpretations of the term "covering." The first possible interpretation is that "covering" refers to the relationship among all possible docking structures, such as in an average. The second interpretation is that "covering" refers to a single docking structure the meets a certain criteria.

In instant claims 4 and 5, the criterion used to "cover" or "select" a docking structure is undefined. Applicant should clarify if the criterion is one of stability, best fit with the ligand, or some other desired property.

In instant claim 5, the process of "selecting stable docking structures" poses a conflict with "rotating torsion angles." If a stable docking structure were chosen, further manipulation of the torsion angles would destabilize the chosen docking structure. Applicant should clarify why stable docking structures are destabilized.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4 and 5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The invention in this instant application is drawn to a series of steps to search for a stable docking molecule. The specification discloses "mathematical" steps used in the process. Inputting information and outputting information can be accomplished through mental steps. No physical steps

are recited in the claims. Thus the invention is directed to "mathematical" steps disclosed in the specification or the "mental steps" in the claims. Mathematical and mental inventions per se are not statutory and are unpatentable.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 4 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by *Pattou et al.* (Journal of Molecular Graphics 10:4).

Pattou et al. teaches a method of molecular modeling that includes three dimensional structures (column 1, 1st paragraph, p 242); intermolecular interactions (column 1, 1st full paragraph, p.241); outputting the stability and structure of docking structures and ligands (Fig. 2, p.242); outputting by structure-optimization steps of torsion which inherently would change the torsion angles (Fig. 3, p 243); and selecting stable docking structures (Column 1, 1st and 2nd paragraph, p 245).

Priority to foreign application Japan 119484/1992 filed 09/27/1992 has not been granted. Applicants are invited to perfect their claim by providing a certified translation of the priority documents.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saunders (Pat. 4,855,931) in view of Tong *et al* (Pharmaceutical Research 8:10).

Saunders teaches a method of modeling optimized 3D molecular structures by inputting three-dimensional coordinates and bond types (column 5, line 55-63). However, Saunders does not teach a method of modeling docking.

Tong *et al.* teach a method of modeling docking molecules, although they do not disclose the details of constructing three-dimensional models (column 1, 3rd full paragraph, p. 1309).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention was made to incorporate Saunders' method with Tong *et al.*'s method. Tong *et al.* does disclose using three-dimensional structures (column 1, 1st paragraph, p. 1309). Thus, a practitioner would have been motivated to use Saunders' method with Tong *et al.* method to take advantage of Saunders' method's ability to calculate the lowest energy molecule without having to input a trial molecular structure (column 3, lines 47-60). Tong *et al.* also disclose testing all possible docking structures between a biopolymer and a ligand for stability and selecting stable docking structures (column 1-2, last paragraph, p. 1309; column 2, last paragraph, p. 1307). Tong *et al.*'s test also searches for the conformation with minimum energy by considering different geometries which would alter the torsion angles of a docking structure.

No claim is allowed.

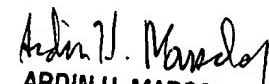
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (703) 306-5439. The examiner can normally be reached on 8:00am-4:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.



Jerry Lin
June 1, 2001



ARDIN H. MARSCHEL
PRIMARY EXAMINER